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| EXAMINER |
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| 1647 | 15 |

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/641,801 | STANTON ET AL. | |
| | Examiner | Art Unit | |
| | Christopher Nichols, Ph.D. | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-4,6-9,11,13-35 and 37-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-9,11 and 13-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5, 6, 12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Status of Application, Amendments, And/Or Claims*

1. The amendments filed 15 October 2002 (Paper No. 11), 4 December 2002 (Paper No. 12), and 14 December 2002 (Paper No. 13) has been entered in full. Claims 1, 6, 11, 20-29, and 31-35 have been amended. Claims 5, 10, 12, and 36 have been cancelled. Claims 37-39 have been added. Claims 1-4, 6-9, and 12-35 are under examination.

2. Applicant's election with traverse of Group 1 (Claims 1-35), in part drawn to methods of contacting cells with SEQ ID NO: 1 in Paper No. 8 (17 July 2002) is acknowledged. The continued traversal is on the ground(s) that examination of 35 SEQ ID NO's would not be a burden and that of the 35 groups would require substantial duplication of work on the part of the USPTO. Applicant further argues that the 35-way restriction is a burden for Applicant in terms of filing and maintenance fees. Finally, Applicant argues that claims 20 and 29 are a linking claims and the restriction should have been a requirement to elect a species. Applicant's arguments have been fully considered but are not found to be persuasive. This is not found persuasive because, with regard to the 35 sequences, examination of specific combinations of peptides requires a significant extension of the search required for the elected peptide. It is noted that the claims recite open claims language. Therefore, the elected invention is drawn to methods comprising contacting cells with SEQ ID NO: 1, and the claims embrace methods wherein cells are contacted with generic compositions comprising SEQ ID NO: 1. While the cost to applicant is regretted, the search required for any one peptide recited in the claims is non-coextensive with the search required for any other. Each peptide requires a unique search of the sequence and literature databases. Therefore, an undue search burden is required of the examiner to search all

of the peptides together. Finally, regarding claims 20 and 29, it appears that claim 20 and 29 is not a linking claim, since the generic "constituent peptide of colostrinin" does not accurately reflect the Markush group recited in Claim 1, for example. The specifically recited peptides are a subgenus. Since each peptide is structurally unique, restriction was proper. See MPEP 809.03. Claims 37-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected material from the restriction requirement, there being no allowable generic or linking claim.

The restriction/election requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-4, 6-9, and 12-35 will be examined to the extent that they read on methods of administering SEQ ID NO: 1, active peptide analogs thereof, and generic compositions comprising the peptide SEQ ID NO: 1.

4. The information disclosure statements filed 18 June 2001 (Paper No. 5), 25 July 2001 (Paper No. 6), and 14 December 2002 (Paper No. 13) have all been considered. It was a clerical oversight on the part of the Examiner that the references in the information disclosure statements filed 18 June 2001 (Paper No. 5), 25 July 2001 (Paper No. 6) were not all initialed. All the references contained in IDS 18 June 2001 (Paper No. 5) and 25 July 2001 (Paper No. 6) were considered at the time of the first office action on the merits 4 September 2002 (Paper No. 10). Copies of initialed, signed, and dated 1449 forms are attached.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Withdrawn Objections And/Or Rejections***

6. The objection to the specification as set forth at pp. 3 of the previous office action (Paper No. 10, 4 September 2002) *is withdrawn in view* of Applicant's correction of the misspelling (Paper No. 12, 4 December 2002).

7. The objection to the specification as set forth at pp. 3 of the previous office action (Paper No. 10, 4 September 2002) *is withdrawn in view* of Applicant's disabled the browser-executable hyperlink text (Paper No. 12, 4 December 2002).

8. The objection to claims 1-19 as reciting non-elected inventions as set forth at p. 4 of the previous Office Action (Paper No. 10, 4 September 2002) is *withdrawn* in view of Applicant's amendments of claims 1-19 (Paper No. 12, 4 December 2002).

9. The rejection of claims 1-35 under 35 U.S.C. 112 first paragraph as set forth at p. 6 of the previous Office Action (Paper No. 10, 4 September 2002) is *withdrawn* in view of Applicant's amendment of claims 20-29 and 31-35 (Paper No. 12, 4 December 2002).

***Maintained Objections And/Or Rejections***

10. Claims 20-35 are objected to because of the following informalities: SEQ ID NO's 2-35 are non-elected inventions pursuant to the restriction requirement 17 June 2002 (Paper No. 7). Applicant's amendment of claims 20-29 and 31-35 has not overcome this objection. The objection to claims 20-35 for reciting non-elected inventions is *maintained.* Appropriate correction is required.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-10 (currently claims 1-4 and 6-9 due to Amendment) are rejected under 35 USC 102(b) as being anticipated by Inglot et al. as set forth at pp. 6-7 of the previous office action (Paper No. 10, 04 September 2002). Applicant's arguments (pp. 14, Paper No. 12, 04 December 2002) have been fully considered but are not found to be persuasive for the following reasons.

13. The Applicant traverses the 35 USC 102(b) rejection of claims 1-10 as set forth in at p. 6-7 of the previous Office Action (Paper No. 10, 4 September 2002) on the grounds that Inglot et al. [(1996) Colostrinine: a Proline-Rich Polypeptide from Ovine Colostrum is a Modest Cytokine Inducer in Human Leukocytes. Archivum Immunologiae et Therapiae Experimentalis 44: 215-224.] does not disclose methods of inducing a cytokine in a cell, modulating an immune response in a cell comprising contacting a cell with a peptide comprising SEQ ID NO: 1, an active analog thereof, and combinations thereof, wherein an "active analog comprises a peptide having an amino acid sequence with at least 15 percent proline and having at least about 70 percent structural similarity to SEQ ID NO: 1". This argument has been taken into consideration and is not found persuasive because Inglot et al. (1996) discloses an active nonapeptide fragment of PRP, NP (V-Q-S-Y-V-P-L-F-P), which contains 22.2% proline and shares structural similarity with SEQ ID NO: 1. NP is 9 residues long and SEQ ID NO: 1 is 7 residues long, therefore NP is 77% structurally similar based on sequence length, a structural characteristic, thus meeting the limitations of claims 1 and 6 (pp. 216 "Materials and Methods"). Inglot et al. (1996) also discloses a method of inducing IFN and TNF (both cytokines) using PRP or NP thus meeting the limitations of claims 1 and 6 (pp. 217 Table 1; pp. 218 Table 3). Inglot et al. (1996) discloses the method of inducing said cytokines in human peripheral blood mononuclear leukocytes (PBL) in

vitro thus meeting the limitations of claims 2, 3, 4, 7, 8, and 9 (pp. 217 Table 1; pp. 218 Table 3). Therefore, Inglot et al. (1996) anticipates claims 1-4 and 6-9 and the 35 USC 102(b) rejection is *maintained.*

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 11-35 (currently claims 11 and 13-35 due to Amendment) are rejected under 35 USC 102(b) as being anticipated by Inglot et al. as set forth at pp. 7-8 of the previous office action (Paper No. 10, 04 September 2002). Applicant's arguments (pp. 14-16, Paper No. 12, 04 December 2002) have been fully considered but are not found to be persuasive for the following reasons.

16. The Applicant traverses the 35 USC 102(b) rejection of claims 11-35 as set forth in at p. 7-8 of the previous Office Action (Paper No. 10, 4 September 2002) on the grounds that WO 98/14473 (9 April 1998 Janusz et al.) does not disclose methods of modulating leukocyte proliferation, wherein proliferation is an increase in cell number, or modulating an immune response in a cell comprising contacting a cell with a peptide comprising SEQ ID NO: 1, an active analog thereof, and combinations thereof, wherein an "active analog comprises a peptide having an amino acid sequence with at least 15 percent proline and having at least about 70 percent structural similarity to SEQ ID NO: 1". The Applicant challenges the use of an inherency argument to apply WO 98/14473 as prior art and discusses case law to support their argument. This argument has been taken into consideration and is not found persuasive because WO

98/14473 (9 April 1998) teaches a method of isolating Colostrinin and defines Colostrinin as including "...analogues and fragments thereof having substantially the same biological activity, and mammalian colostrinin, analogues thereof and fragments thereof produced by recombinant DNA technology. Colostrinin as used herein also include biologically active polypeptides of substantially the same composition as natural colostrinin, which have been made by polypeptide synthesis." (pp. 6 lines 9-16). WO 98/14473 discloses that Colostrinin exhibits cytokine-simulating activity including but not limited to IFN-γ, TNF-α, IL-6, and IL-10. In addition, Colostrinin stimulates the growth, maturation, and differentiation of immune cells, including but not limited to human peripheral blood cultures, lymphocytes, and leukocytes thus meeting the limitations of claims 11, 19, 20, 21, 22, 23, 24, 25, 31, and 32 (pp. 7 lines 23-28; pp. 8 lines 4-11; pp. 9 lines 7-26). WO 98/14473 also discloses that NP (V-G-S-Y-V-P-L-F-P) shares the immunological properties of Colostrinin. NP (V-Q-S-Y-V-P-L-F-P), as discussed above, contains 22.2% proline and shares structural similarity with SEQ ID NO: 1. NP is 9 residues long and SEQ ID NO: 1 is 7 residues long, therefore NP is 77% structurally similar based on sequence length, a structural characteristic, thus meeting the limitations of claims 11, 20, 26, 27, 28, 29, 33, 34, and 35 (pp. 10 lines 5-7). WO 98/14473 also teaches a method of administering Colostrinin or NP to patients orally, as a dietary supplement, and via application to mucus membranes (topically) thus meeting the limitations claims 13, 14, 15, and 16 (Examples II, III, IV, V, X; Table 1; claim 39). Finally, WO 98/14473 claims a method of using Colostrinin or NP in a method for use in the stimulation and/or modulation of the immune system of mammals, including but not limited to humans, thus meeting the limitations of claims 17, 18, and 30 (claims 42-44). Furthermore, WO 98/14473 teaches administration of colostrinin to a patient.

Once administered, colostrinin would inherently and necessarily have caused an increase in leukocytes, thus meeting the limitations of the claims. Finally, "growth, maturation, and differentiation" include proliferation or an increase in cell number (Elgert 1996 "Immunology: Understanding the Immune System: Chapter 10 Cytokines pp. 199-217). Therefore, WO 98/14473 anticipates claims 11, 13-35 and the 35 USC 102(b) rejection is *maintained.*

***Summary***

17. No claims are allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher J. Nichols whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

CJN
February 7th, 2003